

Fact Sheet: May 8, 2024

FSMA FINAL RULE ON PRE-HARVEST AGRICULTURAL WATER: COMPLIANCE DATES AND DOCUMENTATION

On May 6th, 2024, the Food and Drug Administration (FDA) published the final rule to amend the agricultural water provision of the produce safety regulation. This update replaces previous criteria and testing requirements with a new regulatory approach emphasizing systems-based assessments to target key contamination risks, including testing in specific circumstances. It mandates timely risk-based actions and introduces expedited mitigation for certain hazards.

Definitions

Agricultural water assessment: An evaluation of an agricultural water system, agricultural water practices, crop characteristics, environmental conditions, and other relevant factors (including test results, where appropriate) related to growing activities for covered produce (other than sprouts) to

- Identify any condition(s) that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; and
- Determine whether measures are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces with such known or reasonably foreseeable hazards.

Agricultural water system: A source of agricultural water, the water distribution system, any building or structure that is part of the water distribution system (such as a well house, pump station, or shed), and any equipment used for application of agricultural water to covered produce during growing, harvesting, packing, or holding activities.

Effective dates

The rule is effective July 5th, 2024.

Size of covered farm	Proposed compliance date related to pre-harvest agricultural water	Proposed Compliance date related to pre-harvest agricultural water
Very Small Business/Farms	2 years and 9 months after the effective date of this rule.	April 5 th , 2027
Small Business/Farms	1 year and 9 months after the effective date of this rule.	April 6 th , 2026
All Other Businesses/Large Farms	9 months after the effective date of this rule.	April 7 th , 2025

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Documentation and Recordkeeping Requirements

Description	Provision	Record content must include
Agricultural water inspection	§ 112.42 (a)	Annual inspection findings
Written agricultural water assessments	§ 112.43	Description of factors evaluated and written determinations
Alternate index organism, indicator organism, or other analyte, other than testing for generic <i>E. coli</i>	§ 112.43(c)(4)(ii)	Scientific data or information that supports the use of the alternative index organism, indicator organism, or other analyte, other than testing for generic <i>E. coli</i>
Testing frequency and microbial criterion	§ 112.43(c)(4)(ii)	Scientific data or information
Analytical test results	§§ 112.43 and 112.44	Documentation of all analytical tests results
Results or certificates of compliance from a public water system	§ 112.44(c)(1) or (2)	Annual documentation
Actions were taken to reduce the potential for contamination of covered produce of food contact surfaces.	§ 112.45	Documentation of actions <ul style="list-style-type: none"> - Discontinue use - Implementation of mitigation measures
The interval between the last application of agricultural water and the harvest The interval between harvest and end of storage/ other activities during or after harvest	§ 112.45(b)(1)(ii) § 112.45(b)(1)(iii)	Scientific data and information supporting established time interval between application and harvest/ end of storage or other activities during or after harvest
Alternative mitigation measures	§ 112.45(b)(1)(vi)	Scientific data or information relied on to support an alternative mitigation measure that was established and used in accordance with § 112.45(b)(1)(vi).
Water treatment	§ 112.46(a) and (b)	Scientific data and information supporting the adequacy of water treatment and treatment delivery methods
Water treatment monitoring	§ 112.46(c)	Monitoring data using an adequate method and frequency